

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION**

NESTLÉ HEALTH SCIENCE - PAMLAB,  
INC. AND BRECKENRIDGE  
PHARMACEUTICAL, INC.

Plaintiffs,

v.

METHOD PHARMACEUTICALS, LLC,  
J&D LABORATORIES, INC., BRETT  
BARTEL AND ANDREW ROSENTHAL

Defendants.

§ Case No. 3:15-cv-1660-L

§ JURY TRIAL DEMANDED

**FIRST AMENDED COMPLAINT**

Nestlé Health Science – Pamlab, Inc. and Breckenridge Pharmaceutical, Inc. (collectively, “Plaintiffs”), by and through their attorneys, hereby state as follows for their First Amended Complaint against Defendant Method Pharmaceuticals, LLC, J & D Laboratories, Inc., Brett Bartel and Andrew Rosenthal (collectively, “Defendants”):

**I. THE PARTIES**

1. Nestlé Health Science – Pamlab, Inc. (“NHS”) is a Delaware corporation with its principal place of business at 4099 Highway 190, Covington, Louisiana 70433. NHS specializes in the development of medical foods, dispensed by prescription, that are marketed and sold nationally. Among the products NHS markets are four medical foods that are relevant to this lawsuit: Cerefolin NAC<sup>®</sup>, Deplin<sup>®</sup> (in 7.5 mg and 15 mg dosages), and Metanx<sup>®</sup> (collectively, the “NHS Products”).

2. Plaintiff Breckenridge Pharmaceutical, Inc. (“Breckenridge”) is a Florida corporation with its principal place of business at 6111 Broken Sound Parkway, Suite 170, Boca Raton, Florida 33487. Breckenridge markets a broad range of generic prescription products in

many therapeutic categories, including generic versions of the NHS Products, under authority from NHS.

3. Defendant Method Pharmaceuticals, LLC (“Method”) is a Texas limited liability company with its principal place of business at 2000 East Lamar Boulevard, Suite 600, Arlington, Texas 76006. Method markets, promotes, advertises, offers for sale, sells, and distributes allegedly “generic” versions of the NHS Products (“Defendants’ L-Methylfolate Products”), without authorization from NHS, that it labels as containing the same active ingredients in the same strengths as the NHS Products, to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations and/or others throughout the United States, including in the Northern District of Texas. Method may be served with process by serving a copy of the First Amended Complaint on its Registered Agent for service of process: United States Corporation Agents, Inc., located at 9900 Spectrum Drive, Austin, Texas 78717.

4. Defendant J & D Laboratories, Inc. (“J & D”) is a corporation organized under the laws of California with its principal place of business at 2710 Progress Street, Vista, California, 92081. J & D manufactures Defendants’ L-Methylfolate Products for Method. J & D may be served with process by serving a copy of the First Amended Complaint on its Registered Agent for service of process: Kiran H. Majmudar, 2710 Progress Street, Vista, California, 92081

5. Defendant Brett Bob Bartel (“Bartel”) is an individual residing in Marietta, Georgia. Bartel is currently employed by Method where he has responsibilities for, among other things, product development. Bartel was formerly employed as both in-house and outside counsel for Virtus Pharmaceuticals LLC (“Virtus”) where, in the course of prior litigation involving Plaintiffs, he had access to both Virtus’ and Plaintiffs’ highly proprietary technical

information concerning the formulation, development, manufacture, testing, marketing, distribution, pricing and sale of each parties' L-Methylfolate Products. Bartel can be served with process at his residence at 2827 Chapman Way, Marietta, Georgia 30066.

6. Defendant Andrew Rosenthal ("Rosenthal") is an individual residing in Tampa, Florida. Rosenthal is currently employed by Method and is responsible for logistical support. Rosenthal was formerly employed as a Virtus' Business Development and Analytics Manager where he had access to Virtus' highly proprietary information, including the identity of its customers and trade accounts, Virtus' database log-in information, and the formulation, development, marketing, distribution, pricing and sale of Virtus' L-Methylfolate Products. Rosenthal can be served with process at his residence at 1204 E. Cumberland Ave., Unit 207, Tampa, Florida 33602.

## **II. JURISDICTION AND VENUE**

7. This is an action for false advertising and unfair competition under section 43 of the Lanham Act, Title 15 of the United States Code § 1125, common law unfair competition and/or other torts in Texas and other states in which Defendants are conducting their activities. This Court has original jurisdiction over the subject matter of this lawsuit under 28 U.S.C. §§ 1331, 1332 and 15 U.S.C. § 1121(a), because it arises under the Lanham Act. Additionally, the amount in controversy exceeds \$75,000 and involves citizens of different states.

8. This Court has jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367 and the doctrine of supplemental jurisdiction, because the subject matter is so related to the claims asserted under federal law as to form part of the same case or controversy.

9. The exercise of personal jurisdiction in Texas is proper as acts giving rise to Plaintiffs' causes of action have occurred in the State of Texas and more particularly, within the

Northern District of Texas. Defendant Method is a Texas limited liability company, and its principal place of business is 2000 East Lamar Boulevard, Suite 600, Arlington, Texas 76006. It regularly transacts business in Texas. Defendant J & D has entered contracts with Method in Texas and supplies Defendants' L-Methylfolate Products to Method in Texas. Bartel and Rosenthal are employed by Method and provide services to Method in Texas. Bartel and Rosenthal are also members of other limited liability companies formed under Texas law that transact business within the state.

10. Venue is proper in this Court under 28 U.S.C. § 1391(d).

### **III. FACTUAL BACKGROUND**

#### **A. Plaintiff NHS and Its Medical Foods**

11. Plaintiff NHS is a fully integrated pharmaceutical company, founded over 50 years ago, that specializes in the development of prescription medical foods that are marketed and sold nationally.

12. NHS markets its medical foods as a "brand" pharmaceutical company. As such, NHS markets its products directly to physicians educating those physicians concerning the benefits and appropriate uses of its medical food products. NHS has spent millions of dollars calling on tens of thousands of physicians through NHS's sales force, providing millions of product samples, publishing articles and advertisements in medical journals, and funding clinical studies.

13. As described in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. § 360ee(b)(3)), a "medical food" is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on

recognized scientific principles, are established by medical evaluation.” As a therapeutic category, medical foods are distinct from both drugs and dietary supplements.

14. NHS produces four medical foods that are relevant to this lawsuit: Cerefolin NAC<sup>®</sup>, Deplin<sup>®</sup> (in 7.5 mg and 15 mg dosages), and Metanx<sup>®</sup> (collectively, the “NHS Products”). The NHS Products are medical foods that have been formulated to provide the biologically active form of “folate,” to meet the distinct nutritional requirements of patients with certain diseases and medical conditions that may benefit from such a formulation. NHS invested considerable time and money in creating highly proprietary technical and business information concerning the NHS products, including product formulations, validated manufacturing and test methods, sales forecasts, and market strategies. They are the product of many years of experience, dozens of skilled employees' labor, and millions of dollars spent.

15. As medical food products used under a doctor's supervision, the NHS Products are dispensed in response to a prescription.

16. The NHS Products provide the active, naturally occurring form of folate used by the body: 6(S)-5-Methyltetrahydrofolate, also called L-Methylfolate.

17. L-Methylfolate is a distinct compound from its diastereoisomer, D-Methylfolate. Many chemical compounds occur as mixtures of two or more diastereoisomers, which have the same chemical composition, but differ in the spatial arrangement of the atoms. The diastereoisomers may have very different properties from one another. In some cases, one diastereoisomer can have a therapeutic effect, while another diastereoisomer is therapeutically ineffective or even harmful. Thus, there are often great benefits to providing patients and consumers with a product that is diastereoisomerically pure (i.e. contains only a single diastereoisomer as opposed to a diastereoisomeric mixture).

18. Diastereoisomers are distinguished from one another through naming conventions that reflect their different properties. One such naming convention uses an “L” in the name of the compound to indicate one diastereoisomer, and a “D” in the name of the compound for a different diastereoisomer. The L-form of this compound used in the NHS Products – *i.e.*, L-Methylfolate – is superior to the D-form of this compound (D-Methylfolate) because the L-form is the naturally occurring predominant form of folate found in food and the human body. The L-form is the biologically active form of folate and has proven to have a high degree of bioavailability (the rate at which a drug or other substance is available at the targeted place in the body) in humans. The D-form, on the other hand, is of no benefit to humans.

19. L-Methylfolate can be synthesized in commercial quantities as an amorphous salt. However, in this form, it is highly unstable and degrades quickly, making it unsuitable for use in pharmaceutical products.

20. The NHS Products use Metafolin<sup>®</sup>, a patented, highly stable crystalline form of L-Methylfolate. Metafolin<sup>®</sup> is a substantially diastereoisomerically pure source of L-Methylfolate that contains not more than 1% D-Methylfolate. This ingredient was accepted by the FDA as a food additive and is generally recognized as safe (GRAS). Unlike other forms of L-Methylfolate, Metafolin<sup>®</sup> is stable and suitable for use in pharmaceutical products. NHS uses the presence of the dietary ingredient L-Methylfolate (Metafolin<sup>®</sup>) as a primary selling point for its products.

**B. The NHS-Breckenridge Joint Venture and the Authorized Generic Products**

21. Plaintiff Breckenridge, in contrast to NHS, is a generic pharmaceutical company. For more than 25 years Breckenridge has been in the business of developing and marketing generic pharmaceutical products, and it currently markets more than 70 such products.

22. Breckenridge and NHS have entered into a Joint Venture wherein Breckenridge sells generic versions of the NHS Products, under authority from NHS. Breckenridge sells Metafolbic™ Plus RF, L-Methylfolate Forte (7.5 mg and 15 mg), and Foltnx™ RF (the “Breckenridge Generic Products”), which correspond to Cerefolin NAC®, Deplin® (7.5 mg and 15 mg), and Metanx®, respectively. The NHS Products and the Breckenridge Generic Products may be referred to below, collectively, as “Plaintiffs’ L-Methylfolate Products.”

23. The Breckenridge Generic Products have the identical ingredients – including the same pure L-Methylfolate ingredient (Metafolin®) – in the same strengths as the corresponding NHS Products. NHS manufactures the Breckenridge Generic Products for Breckenridge in the same facility, using the same quality, purity and performance specifications it uses for the NHS Products. The Breckenridge Generic Products are identical in every way to the NHS Products except for imprint and labeling, and may be dispensed as substitutes for prescriptions written for the NHS Products.

24. NHS and Breckenridge share in the profits generated by sales of the Breckenridge Generic Products.

**C. NHS and Breckenridge Successfully Defended Their Products From False Advertising and Unfair Competition By Virtus**

25. NHS (and, through it, Breckenridge) hold an exclusive license in the United States to use patented Metafolin® (the stable, pure, and crystalline form of L-Methylfolate) in medical foods. No other company is authorized to purchase and use the patented, stable, pure and crystalline form of the ingredient in developing an equivalent, generic version of Plaintiffs’ medical foods. Some companies have resorted to either using a different ingredient altogether, such as folic acid or racemic D,L-Methylfolate, or an amorphous and unstable form of L-Methylfolate available from certain suppliers in China and India.

26. Florida-based Virtus Pharmaceuticals, LLC (“Virtus”) used an amorphous and unstable form of L-Methylfolate in products Virtus falsely labeled and advertised as equivalent generics to Plaintiffs’ Cerefolin NAC<sup>®</sup>, Deplin<sup>®</sup> (7.5 mg and 15 mg), and Metanx<sup>®</sup>. Virtus’ products were not stable and were not equivalent generics to Plaintiffs’ products. Plaintiffs brought suit against Virtus for false advertising. *Nestle Health Science - Pamlab, Inc. and Breckenridge Pharmaceutical, Inc. v. Virtus Pharmaceuticals, LLC*, Case No. 9:12-cv- 81202-KMW (S.D. Fla.) (the “*Virtus* litigation”).

27. In August 2014, Plaintiffs and Virtus tried the *Virtus* litigation. After the case went to the jury but before a verdict, the parties settled the case. As part of its settlement agreement with Plaintiffs, Virtus agreed to halt sales of L-Methylfolate capsules. NHS agreed to allow Virtus to sell L-Methylfolate tablets manufactured and sold by NHS. As part of this agreement, Virtus further promised that for a specified time period extending beyond the present, neither Virtus nor its affiliates would assist any third party in manufacturing, using, marketing or selling any product given the same database code by pharmaceutical databases as the currently marketed versions of Cerefolin NAC<sup>®</sup>, Deplin<sup>®</sup> 7.5 mg, Deplin<sup>®</sup> 15 mg and Metanx.<sup>®</sup>

28. Bartel is a lawyer, and was employed by Virtus as counsel of record during the *Virtus* litigation, first through his firm Taylor English Duma LLP, and also for a period of time as in-house counsel. Within just a few months of Virtus hiring Bartel as an employee and in-house counsel, Bartel proposed returning to outside-counsel status so that he would not be barred from reviewing “Outside Attorney Eyes Only” documents in litigation. Therefore, he nominally resumed his position with Taylor English Duma LLP, while continuing to occupy Virtus’ leased office and to receive a monthly salary from Virtus, and while remaining enrolled in Virtus’ employee health insurance plan – all without Plaintiffs knowledge.

29. As Virtus' counsel of record in the *Virtus* litigation, Bartel had access to all of Virtus' documents and information regarding its L-Methylfolate products, practices and suppliers, including among other things: (a) the identities of its trade-secret active pharmaceutical ingredients ("APIs"); (b) the chemical properties and effective combinations of its APIs and the various inactive pharmaceutical ingredients, stabilizers, and overages, in each product; (c) the precise ingredient formulations necessary for product efficacy; (d) the identities and capabilities of specialized API manufacturers; (e) the identities and capabilities of contract manufacturing organizations that make the finished product; (f) the pricing arrangements with entities throughout the supply chain; and (g) the techniques for achieving product linkage in pharmaceutical databases and for marketing new products at lower prices than competing products.

30. As a lawyer identified in the pleadings as outside counsel, Bartel also had access to Plaintiffs' sensitive "Confidential" or "Confidential – Outside Attorney's Eyes Only" information about Plaintiffs' L-Methylfolate Products. This information was produced by Plaintiffs in discovery pursuant to the *Virtus* Court's protective order and includes information about product formulation, database linkages, manufacturing, test methods, pricing, profits and customers.

31. The *Virtus* Court's protective order expressly prohibited use of information designated as "Confidential" or "Confidential – Outside Attorney's Eyes Only" outside the context of the litigation or for business purposes. It also prohibited disclosure of such information to anyone not qualified to have access to the information under the order's terms, including Virtus and its employees. It also contained provisions to prevent access to such information by persons who might be a competitor of the producing party.

32. As Virtus' attorney, Bartel owed fiduciary duties to Virtus. As Virtus' employee and attorney, he was presumptively controlled by Virtus and was its affiliate. As one of its attorneys, Bartel was aware of the settlement agreement between Plaintiffs and Virtus, and knew its terms.

33. Andrew Rosenthal was employed by Virtus as a business development and analytics manager from sometime in 2013 until approximately May 2015, including during the *Virtus* litigation.

34. As Virtus' employee during the *Virtus* litigation, Rosenthal had access to Virtus' documents and information regarding its L-Methylfolate products, practices and suppliers, including among other things: (a) the identities of its trade-secret APIs; (b) the chemical properties and effective combinations of its APIs and the various inactive pharmaceutical ingredients, stabilizers, and overages, in each product; (c) the precise ingredient formulations necessary for product efficacy; (d) the identities and capabilities of specialized API manufacturers; (e) the identities and capabilities of contract manufacturing organizations that make the finished product; (f) the pricing arrangements with entities throughout the supply chain; and (g) the techniques for achieving product linkage in pharmaceutical databases and for marketing new products at lower prices than competing products.

35. As Virtus' employee, Rosenthal was presumptively controlled by Virtus and was its affiliate at the time Plaintiffs entered their settlement agreement with Virtus. Upon information and belief, Rosenthal was aware of the settlement agreement between Plaintiffs and Virtus, and knew its terms.

36. Upon information and belief, while still employed by Virtus, Bartel and Rosenthal began making plans to form a new venture to develop, manufacture, advertise, market, promote, sell and/or distribute L-Methylfolate products in competition with Plaintiffs.

**D. Defendants' Knock-Off L-Methylfolate Products**

37. Method is a Texas-based, generic drug distributor that purports to develop, manufacture, market and sell what it calls "specialty pharmaceuticals." On information and belief, Method does not market its pharmaceutical products to physicians. Rather, it convinces pharmaceutical wholesalers, distributors, pharmacies, pharmacists and national drug databases that its products are "generics" or substitutes for brand-name pharmaceutical products. Its sales result from "generic" substitution of its products for brand-name drugs.

38. On information and belief, Method promotes, markets, sells and distributes its products nationwide, including in Texas and this judicial district.

39. Method has employed Bartel since at least October 2014 for services relating to product development, but kept his employment secret until a third party disclosed that fact to Plaintiffs at the end of January 2016.

40. On information and belief, Method knew that Bartel and Rosenthal had Virtus' and/or Plaintiffs' documents and information regarding their L-Methylfolate products, practices and suppliers. On information and belief, Method knew that as former Virtus employees, Bartel and Rosenthal were contractually barred from helping Method to develop, manufacture, use, market or sell any product given the same database code by pharmaceutical databases as the currently marketed versions of Cerefolin NAC<sup>®</sup>, Deplin<sup>®</sup> 7.5 mg, Deplin<sup>®</sup> 15 mg and Metanx<sup>®</sup>.

41. Sometime in 2014, Method, Bartel and Rosenthal decided to exploit the reputation and success of Plaintiffs' L-Methylfolate Products by creating knock-off products

(hereafter “Defendants’ L-Methylfolate Products”). Defendants’ L-Methylfolate Products include:

- Levomefolate Calcium/Acetylcysteine/Mecobalamin/Algal Powder Caplets (NDC No. 58657-202);
- Levomefolate Calcium/Algal Powder Capsules (7.5 mg) (NDC No. 58657-205);
- Levomefolate Calcium/Algal Powder Capsules (15 mg) (NDC No. 58657-208); and
- Levomefolate Calcium/Pyridoxal-5 Phosphate/Mecobalamin/Algal Powder Capsules (NDC No. 58657-211).

42. According to Method, Bartel – a lawyer – was responsible for the research, development, manufacturing, testing and advertising of Defendants’ L-Methylfolate Products as well as the composition, formulation and specifications of the L-Methylfolate ingredient used in Defendants’ L-Methylfolate Products. According to Method, we was also responsible for the “linking” or cross-referencing of Defendants’ L-Methylfolate Products in industry databases.

43. On information and belief, Bartel and Rosenthal gave Method confidential and trade secret information belonging to Virtus and/or Plaintiffs concerning the formulation, development, manufacturing, distribution, testing, marketing, advertising and sale of products containing L-Methylfolate. On information and belief, Method used Bartel and Rosenthal’s knowledge of Virtus’ and/or Plaintiffs’ confidential and trade secret information in formulating, developing, manufacturing, distributing testing, listing, marketing, distributing and selling Defendants’ L-Methylfolate Products. For example, Method uses the very same Indian and Chinese sources of amorphous and unstable L-Methylfolate in Defendants’ L-Methylfolate Products that Virtus used in its inferior products. Method also uses the same testing laboratories and, upon information and belief, testing methods that Virtus used. Upon information and belief, Method and J & D use information concerning ingredient overages and formulations for the

Method Products that Bartel and/or Rosenthal learned as employees of Virtus. Upon information and belief, Method uses information concerning product pricing for the Method Products that Bartel and/or Rosenthal learned as employees of Virtus.

44. At the time Method, Bartel and/or Rosenthal acquired Virtus and/or Plaintiffs' trade secret information, Method, Bartel and/or Rosenthal knew that this information was proprietary to Virtus and Plaintiffs. Bartel and Rosenthal also knew that assisting Method in developing, manufacturing, marketing and selling the Method Products in competition with Plaintiffs constituted a breach of the settlement agreement between Plaintiffs and Virtus.

45. On information and belief, Method used Bartel and/or Rosenthal's knowledge of Virtus and Plaintiffs' confidential and trade secret information, including information about contracts, pricing, customers, and database linkages, to market the Method Products to Plaintiffs' customers in competition with Plaintiffs, thereby deriving an economic value from Virtus' and Plaintiffs' confidential information. On information and belief, Method also used Bartel and/or Rosenthal's knowledge of Virtus' and Plaintiffs' confidential and trade secret information, to develop, formulate and manufacture L-Methylfolate tablet products that Method has either launched or will soon launch to compete with sales of Virtus' L-Methylfolate tablet products that Virtus markets under its agreement with NHS.

**E. Method Markets Defendants' L-Methylfolate Products as containing the same ingredients in the same strength and as generic equivalents to the NHS Products**

46. In its commercial advertising and promotion, including specifically its labels, package inserts and other documents (including documents provided to the FDA), Method claims Defendants' L-Methylfolate Products have the same ingredients, including "L-Methylfolate Calcium\*" (\*CAS 151533-22-1), in the same strengths as Cerefolin NAC<sup>®</sup>, Deplin<sup>®</sup> 7.5 mg, Deplin<sup>®</sup> 15 mg, and Metanx<sup>®</sup>, respectively.

47. Upon information and belief, in its commercial advertising and promotion to drug databases, wholesalers, pharmacies, pharmacists and others (the “pharmaceutical distribution chain”), Method has made no effort to differentiate Defendants’ L-Methylfolate Products from the NHS Products other than on the basis of price. Instead, on information and belief, Method markets Defendants’ L-Methylfolate Products to the pharmaceutical distribution chain as generic equivalents to and substitutes for the NHS Products. In furtherance of its promotional scheme and with Bartel and Rosenthal’s assistance, Method has had its knock-off products “linked” to the NHS Products as equivalents in pharmaceutical databases that represent a major marketing communications channel to pharmaceutical wholesalers, pharmacies and others, and that are used by pharmacists to decide which product to dispense when filling a prescription.

48. Upon information and belief, Method seeks to capture market share from Plaintiffs’ L-Methylfolate Products by encouraging generic substitution of Defendants’ L-Methylfolate Products for prescriptions written by health care providers for the NHS Products.

49. J & D is well aware that Method advertises and promotes Defendants’ L-Methylfolate Products as using the same active ingredients in the same amounts as Plaintiffs’ L-Methylfolate Products, and as generic equivalents to and substitutes for the NHS Products.

50. Method’s efforts have had their intended effect; based upon Method’s commercial advertising and promotion, pharmaceutical databases as well as wholesalers, pharmacies and others have linked Defendants’ L-Methylfolate Products to the NHS Products as generic equivalents.

51. As a result of Defendants’ commercial advertising and promotion, wholesalers and pharmacies in the Northern District of Texas and across the country have purchased or will purchase Defendants’ L-Methylfolate Products and have ceased or will cease to purchase

Plaintiffs' L-Methylfolate Products, believing that the Defendants' L-Methylfolate Products are available as generic substitutes. This could not occur unless Method had successfully created the false impression among pharmaceutical databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical distribution chain that Defendants' L-Methylfolate Products contain the ingredients in the same strengths as Plaintiffs' L-Methylfolate Products and that they are generic to and substitutable for the NHS Products.

**F. Method Marketed Defendants' L-Methylfolate Products as Drugs**

52. The Drug Listing Act of 1972 requires registered drug companies to provide the FDA with a current list of all human drugs they manufacture or label for commercial distribution. These companies identify their drug products using a unique, three-segment number, called the National Drug Code (NDC). The FDA publishes information submitted by drug establishments about their drug products in the NDC Directory.

53. It is unlawful to assign an NDC number to a non-drug product.

54. Defendant Method claimed its L-Methylfolate Products are drugs in the information it provided to the FDA. As a result, Defendants' L-Methylfolate Products were assigned NDC numbers and identified in the FDA's NDC Directory as "human prescription drugs." For example, the NDC Directory listed Defendants' Levomefolate Calcium/Algal Powder Capsules (7.5 mg) as follows:

| Method Pharmaceuticals, LLC   58657-205-90   Levomefolate Calcium and Algal (levomefolate calcium and schizochytrium dha oil)   CAPSULE   7.5 mg/1, 90.314 mg/1 |   |
|---|---|
| Product NDC:  | 58657-205                                       |
| Proprietary Name:   | Levomefolate Calcium and Algal                  |
| Non-Proprietary Name:   | levomefolate calcium and schizochytrium dha oil |
| Product Type Name:  | HUMAN PRESCRIPTION DRUG                         |
| Market Category Name:   | UNAPPROVED DRUG OTHER                           |
| Application Number:   |   |
| Route Name:   | ORAL  |
| Substance Name:   | LEVOMEFOLATE CALCIUM; SCHIZOCHYTRIUM DHA OIL    |
| Package Description:  | 90 CAPSULE in 1 BOTTLE (58657-205-90)           |
| Pharm Class:  | N/A   |
| DEA:  | N/A   |
| Labeler Name:   | Method Pharmaceuticals, LLC                     |
| Start date:   | 04-01-2015 / End date:                          |

Although Method claims that its NDC Directory listings have been “deactivated”, the FDA continues to list the Defendants L-Methylfolate products as “human prescription drugs.” The pharmaceutical distribution chain relies on information the FDA publishes in the NDC Directory and elsewhere to identify drugs eligible for insurance reimbursement. Governmental (e.g., Medicaid) and private insurers provide insurance coverage for many types of human prescription drugs. However, Medicaid and many private insurers do not cover medical foods such as the Plaintiffs’ L-Methylfolate Products.

55. As a result of Defendants’ commercial advertising and promotion through the NDC Directory and elsewhere, wholesalers and pharmacies in the Northern District of Texas and across the country purchased Defendants’ L-Methylfolate Products in lieu of Plaintiffs’ L-Methylfolate Products, believing that Defendants’ L-Methylfolate Products are eligible for insurance reimbursement while Plaintiffs’ L-Methylfolate Products are not. This could not occur unless Method had successfully created the false impression among drug databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical distribution chain that Defendants’ L-Methylfolate Products are human prescription drugs.

**G. Method’s Advertising is Literally False and Misleading**

**(a) Defendants’ L-Methylfolate Products Do Not Have the Same Active Ingredients in the Same Amounts as Plaintiffs’ L-Methylfolate Products**

56. Notwithstanding Method’s commercial advertising and promotion, Defendants’ L-Methylfolate Products do not have the same active ingredients in the same amounts as Plaintiffs’ L-Methylfolate Products.

57. Method and J & D do not use the same pure and stable crystalline L-Methylfolate ingredient used in Plaintiffs’ L-Methylfolate Products. Instead, Method and J & D utilize the same impure, amorphous and unstable form of L-Methylfolate Calcium that Virtus used in its L-

Methylfolate products. The use of this impure, amorphous and unstable ingredient in the manufacture of Defendants' L-Methylfolate Products leads to inferior, sub-standard and unstable finished products. Upon information and belief, when Method tested the potency and stability of the initial batches of Defendants' L-Methylfolate Products, these products failed to meet potency and stability criteria, but Method launched the product anyway.

58. As the manufacturer of Defendants' L-Methylfolate Products, J & D is well aware that Defendants' L-Methylfolate Products use an impure, amorphous and unstable form of L-Methylfolate Calcium, and the use of this ingredient leads to inferior, sub-standard and unstable finished products. J & D nevertheless supplies these knock-off products to Method.

**(b) Defendants' L-Methylfolate Products Are Not Generic Equivalents to or Substitutes for the NHS Products**

59. A pharmacist presented with a doctor's prescription for a brand-name product may fill that prescription by dispensing the product prescribed or an identical, "generic" version of the product. This process is known as generic substitution.

60. A generic pharmaceutical product is identical – or bioequivalent – to a brand name product in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. It is the same as a brand-name product in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. It must have the same high quality, strength, purity and stability as the brand-name product.

61. Notwithstanding Method's express and implied representations in its commercial advertising and promotion, Defendants' L-Methylfolate Products are not generic equivalents to or substitutes for Plaintiffs' L-Methylfolate Products because they do not have the identical L-Methylfolate ingredient, strength, quality, performance characteristics and/or intended use. Instead they use an impure, amorphous and unstable form of L-Methylfolate Calcium. The use

of this material leads to inferior, sub-standard and unstable finished products that do not retain their potency for the duration of their labeled shelf-life.

**(c) Defendants' L-Methylfolate Products are Not Human Prescription Drugs that are Reimbursable**

62. Notwithstanding Defendants' commercial advertising and promotion, Defendants' L-Methylfolate Products are not human prescription drugs eligible for reimbursement. Drugs are defined as:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

63. Furthermore any "new" drug must be have an approved New Drug Application. Defendants' L-Methylfolate Products are not listed in the Homoeopathic Pharmacopoeia or the National formulary. Nor are they intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body. Defendants' L-Methylfolate Products are not the subject of an approved New Drug Application. Thus, Defendants' L-Methylfolate Products are not drugs.

**COUNT I**

**FALSE ADVERTISING IN VIOLATION OF  
THE LANHAM ACT, 15 U.S.C. § 1125(A)**

64. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

65. In its commercial advertising and promotion to drug databases, wholesalers, pharmacies, pharmacists and others in interstate commerce, Method represents that Defendants' L-Methylfolate Products have the same ingredients in the same strength as Plaintiffs' L-

Methylfolate Products, are generics to and substitutes for Plaintiffs' L-Methylfolate Products, and are drugs. Method intend for pharmaceutical databases, wholesalers, pharmacies, pharmacists and others to believe that Defendants' L-Methylfolate Products are equivalent to and substitutable for Plaintiffs' L-Methylfolate Products, and to purchase Defendants' L-Methylfolate Products in place of Plaintiffs' L-Methylfolate Products. By describing its L-Methylfolate Products as "human prescription drugs" Method further intended pharmaceutical databases, wholesalers, pharmacies, pharmacists and consumers to believe that Defendants' L-Methylfolate Products are eligible for reimbursement by governmental and private insurers.

66. Method's promotional claims about Defendants' L-Methylfolate Products are literally and/or impliedly false and misleading. Defendants' L-Methylfolate Products do not have the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products; they are not equivalent to, generic to, or substitutable for Plaintiffs' L-Methylfolate Products, and they are not drugs eligible for reimbursement. Method's promotional claims violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which provides in relevant part that

any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable to a civil action by any person who believes that he or she is likely to be damaged by such act.

67. J & D is liable for false advertising under the Lanham Act because it knows of Method's false and misleading advertising of Defendants' L-Methylfolate Products but continues to supply Defendants' L-Methylfolate Products to Method anyway.

68. Additionally, Method and J & D are liable for false advertising under the Lanham Act because they intentionally induced and/or knew or had reason to know that the government, pharmaceutical databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical

distribution chain would falsely describe Defendants' L-Methylfolate Products as having the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products, as generic to and substitutable for Plaintiffs' L-Methylfolate Products, and as drugs to pharmacists, but continued to market and sell the products to those entities.

69. Upon information and belief, Method has also made other false and/or misleading representations of fact that misrepresent the nature, characteristic, or qualities of Defendants' L-Methylfolate Products.

70. Method's false and misleading explicit and/or implicit representations go to an inherent quality or characteristic of Defendants' L-Methylfolate Products. Thus, Method's false and misleading explicit and/or implicit representations are material, have influenced or will influence purchasing decisions in this District and elsewhere, and will continue to do so unless enjoined.

71. By reason of Defendants' conduct, Plaintiffs have suffered or are likely to suffer, damage to their business, reputations, and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendants' Lanham Act violations, an accounting of profits made by Defendant on sales of Defendants' L-Methylfolate Products, and recovery of Plaintiffs' costs for this action.

72. Defendants' acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

73. Unless enjoined by this Court, Defendants' acts will irreparably injure Plaintiffs' goodwill and erode their market share. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts.

74. Upon information and belief, Defendants will continue their violation of the Lanham Act unless this violation is restrained and enjoined by this Court. Due to Defendants' continuing acts of false advertising, Plaintiffs have suffered and/or will suffer irreparable injury for which they have no adequate remedy at law.

**COUNT II**

**UNFAIR COMPETITION IN VIOLATION OF  
THE LANHAM ACT, 15 U.S.C. § 1125(A)**

75. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

76. Plaintiffs have become uniquely associated with the Plaintiffs' L-Methylfolate Products, and the public identifies Plaintiffs as the source for Plaintiffs' L-Methylfolate Products.

77. In its commercial advertising and promotion to drug databases, wholesalers, pharmacies, pharmacists and others in interstate commerce, Method represents that Defendants' L-Methylfolate Products have the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products, are generics to and substitutes for Plaintiffs' L-Methylfolate Products, and are drugs. In doing so, Method has deceived, misled, and confused pharmaceutical databases, wholesalers, pharmacies, pharmacists and consumers as to the nature, characteristics and qualities of Defendants' L-Methylfolate Products in comparison, connection or association with Plaintiffs' L-Methylfolate Products. This has enabled Method to trade off of Plaintiffs' reputation and good will.

78. Method's acts constitute unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

79. J & D is liable for unfair competition under the Lanham Act because it knows of Method's false and misleading advertising of Defendants' L-Methylfolate Products but continues to supply Defendants' L-Methylfolate Products to Method.

80. Additionally, Method and J & D are liable for unfair competition under the Lanham Act because they intentionally induced and/or knew or had reason to know that the government, pharmaceutical databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical distribution chain falsely describe Defendants' L-Methylfolate Products as having the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products, as generic to and substitutes for the Plaintiffs' L-Methylfolate Products, and as drugs to pharmacists, but continued to market and sell the products to those entities.

81. By reason of Defendants' conduct, Plaintiffs have suffered or are likely to suffer, damage to their business, reputations, and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendants' Lanham Act violations, an accounting of profits made by Defendants on sales of Defendants' L-Methylfolate Products, and recovery of Plaintiffs' costs for this action.

82. Defendants' acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

83. Unless enjoined by this Court, Defendants' acts will irreparably injure Plaintiffs' goodwill and erode its market share. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts.

**COUNT III**  
**COMMON LAW UNFAIR COMPETITION**

84. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

85. With full knowledge of Plaintiffs' L-Methylfolate Products, Defendant Method made false and misleading explicit and implicit representations in its commercial advertising and promotion to drug databases, wholesalers, pharmacies, pharmacists and others in interstate commerce, that Defendants' L-Methylfolate Products have the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products, are generics to and substitutes for Plaintiffs' L-Methylfolate Products, and are drugs.

86. Defendant Method's false and misleading statements and omission of relevant facts are likely to cause and have caused confusion, mistake or deception about the nature, characteristics and qualities of Defendants' L-Methylfolate Products in comparison, connection or association with Plaintiffs' L-Methylfolate Products.

87. Defendant Method knows, or in the exercise of reasonable discretion should know, that its advertising deceives potential customers about the nature, characteristics and qualities of Defendants' L-Methylfolate Products in comparison, connection or association with Plaintiffs' L-Methylfolate Products.

88. Defendant Method's conduct amounts to deception, trickery and/or unfair methods and has damaged and jeopardized Plaintiffs' businesses. As a result of such malicious, wanton and/or fraudulent conduct, Defendant has caused, will cause, and unless enjoined by the Court, will continue to cause confusion as to the substitutability for and equivalence of its knockoff products with Plaintiffs' L-Methylfolate Products.

89. Additionally, J & D is contributorily liable for unfair competition because it knows or has reason to know of and/or assisted Method's false and misleading advertising describing Defendants' L-Methylfolate Products as generic equivalents to and substitutes for the NHS Products, yet aided and abetted those violations.

90. Additionally, Method and J & D have unfairly competed with Plaintiffs by misappropriating Plaintiffs' confidential and highly confidential technical and business information about their L-Methylfolate products, including information about product formulation, database linkages, manufacturing, test methods, pricing, profits and customers, for use in developing, formulating, manufacturing, using, selling, offering to sell, distributing, advertising, promoting and marketing the Method Products. This information was created by Plaintiffs through investment of extensive time, labor, skill, and money. Defendants improperly acquired and used this information in competition with Plaintiffs, thereby giving the Defendants a special competitive advantage because they were burdened with little or none of the expenses incurred by Plaintiffs in the creation of L-Methylfolate products.

91. As a result of Method and J & D's conduct, Plaintiffs have suffered, and unless such acts and practices are enjoined by this Court, will continue to suffer, damage to their business, reputation and goodwill for which they are entitled to relief.

92. Plaintiffs are entitled to damages for Method and J & D's unfair competition, an accounting of profits made on sales of Defendants' L-Methylfolate Products, and recovery of Plaintiffs' costs of this action. Defendants' actions have been willful and undertaken with the purpose of deceiving consumers. Thus, Plaintiffs are entitled to an award of punitive damages.

**COUNT IV:**  
**TORTIOUS INTERFERENCE WITH CONTRACT (as to Method)**

93. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

94. Plaintiffs negotiated and executed a valid and enforceable settlement agreement with Virtus that imposed duties on Virtus and its affiliates not to market, or to assist any third party in manufacturing, using, marketing or selling any product given the same database code by pharmaceutical databases as the NHS Products.

95. As Virtus' counsel of record during the *Virtus* litigation at the time the settlement agreement was entered, Bartel knew the terms of the settlement agreement. As Virtus' outside and in-house counsel at the time the settlement agreement was entered, Bartel was presumptively under Virtus' control, was an affiliate of Virtus, and was bound by the terms of the settlement agreement.

96. Upon information and belief, Rosenthal knew the terms of the settlement agreement. As Virtus' employee at the time the settlement agreement was entered, Rosenthal was presumptively under Virtus' control, was an affiliate of Virtus, and was bound by the terms of the settlement agreement.

97. With knowledge of Virtus, Bartel and Rosenthal's existing contractual duties, Method improperly induced Virtus, Bartel and/or Rosenthal to breach the settlement agreement by inducing Bartel and Rosenthal to assist Method in formulating, developing, manufacturing, using, selling, offering to sell, distributing, advertising, promoting and marketing the Method Products, and in linking the Method Products to Plaintiffs' L-Methylfolate Products in pharmaceutical databases.

98. As a direct and proximate result of Method's actions, Virtus, Bartel and/or Rosenthal breached the settlement agreement with Plaintiffs.

99. Method lacked any legally recognized justification, privilege or excuse for interfering with the settlement agreement.

100. Method's inducement of breach was willful, malicious, and in conscious disregard for Plaintiffs' rights. Method intended to secure an unfair business advantage at the expense of and injury to Plaintiffs.

101. Method's interference with Plaintiffs' settlement agreement with Virtus directly and proximately injured Plaintiffs, in an amount to be proven at trial.

102. Plaintiffs have no adequate remedy at law for Method's interference with the settlement agreement.

103. Plaintiffs are therefore also entitled to preliminary and permanent injunctive relief enjoining Method from further acts of interference with the settlement agreement.

**COUNT V:**  
**TORTIOUS INTERFERENCE WITH CONTRACT (as to Bartel and Rosenthal)**

104. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein

105. Plaintiffs negotiated and executed a valid and enforceable settlement agreement with Virtus that imposed duties on Virtus and its affiliates not to assist any third party to engage in any manufacture, use, marketing or sale of any third party's product given the same database code by pharmaceutical databases as the NHS Products.

106. As Virtus' counsel of record during the *Virtus* litigation at the time the settlement agreement was entered, Bartel knew the terms of the settlement agreement. As Virtus' counsel, Bartel owed fiduciary duties to Virtus to avoid impermissible conflicting interests, and not to

employ advantages arising from the client-lawyer relationship in a manner adverse to the client. As Virtus' outside and in-house counsel at the time the settlement agreement was entered, Bartel was presumptively under the control of Virtus and thus an affiliate of Virtus.

107. As Virtus' employee at the time the settlement agreement was entered, and upon information and belief, Rosenthal knew the terms of the settlement agreement. As Virtus' employee at the time the settlement agreement was entered, Rosenthal was presumptively under the control of Virtus and thus an affiliate of Virtus.

108. With knowledge of Virtus' existing contractual duties, Bartel and/or Rosenthal improperly induced Virtus to breach the settlement agreement with Plaintiffs by assisting Method in developing, formulating, manufacturing, selling and distributing the Method Products, and in linking the Method Products to Plaintiffs' L-Methylfolate Products with the same database code in pharmaceutical databases.

109. Bartel and/or Rosenthal's actions were taken in furtherance of their personal interests, contrary to the best interests of Virtus, and were not taken in good faith.

110. Bartel and/or Rosenthal lacked any legally recognized justification, privilege or excuse for interfering with the settlement agreement. Bartel and/or Rosenthal's inducement of breach was willful, malicious, and in conscious disregard of Plaintiffs' rights.

111. Bartel and/or Rosenthal's interference with Plaintiffs' settlement agreement with Virtus directly and proximately injured Plaintiffs, in an amount to be proven at trial.

112. Plaintiffs have no adequate remedy at law for Bartel and/or Rosenthal's interference with the settlement agreement.

113. Plaintiffs are therefore also entitled to preliminary and permanent injunctive relief enjoining Bartel and Rosenthal from further acts of interference with the settlement agreement.

**COUNT VI:**  
**TORTIOUS INTERFERENCE WITH BUSINESS RELATIONS**

114. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein

115. NHS' settlement agreement with Virtus concerning the sale of L-Methylfolate tablet products establishes an ongoing business relationship between NHS and Virtus and provides a substantial probability of future benefits to NHS. NHS's current and future economic benefits that flow from these contractual relationships form a business expectancy. These economic benefits are capable of quantification and are not speculative or remote.

116. During and after their respective periods of employment with Virtus, Defendants Bartel and Rosenthal were aware of the settlement agreement between Plaintiffs and Virtus and the business expectancy interests provided to NHS by virtue of Virtus' marketing and sale of L-Methylfolate tablets as provided by this agreement.

117. Method was aware that Bartel and Rosenthal were restricted from disclosing or using Virtus' trade secrets and other confidential and proprietary business information after leaving Virtus' employment.

118. Upon information and belief, Method is preparing to link and launch L-Methylfolate tablet products that will compete with L-Methylfolate tablets sold by Virtus. Method's ability to successfully link and launch competing L-Methylfolate tablet products stems directly from the use of Virtus' trade secrets and confidential/proprietary information stolen by Bartel and Rosenthal.

119. Method knows and intends for sales of its L-Methylfolate tablet product to displace Virtus' sales of L-methylfolate tablet products, thereby reducing Virtus' sales, and both Virtus and NHS' revenues.

120. Thus by their misappropriation of Virtus' trade secrets and their subsequent development, marketing, and sale of L-Methylfolate tablet products on behalf of defendant Method, Defendants intentionally interfered with NHS's valid business relationship with Virtus.

121. Defendants' interference with NHS' business relationship has caused damages to NHS, in the form of diminished revenue and other damages.

122. There is a reasonable certainty that absent Defendants' intentional conduct, NHS would have realized the full economic benefits of its contractual relationship with Virtus.

**COUNT VII:**  
**MISAPPROPRIATION OF TRADE SECRETS IN VIOLATION OF THE TEXAS  
UNIFORM TRADE SECRETS ACT, TEX. CIV. PRAC. & REM. CODE ANN. § 134A**

123. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

124. Plaintiffs own confidential and proprietary information pertaining to their L-Methylfolate product formulation, manufacturing and test methods, pricing and customers. This includes information about how to manufacture and test stable finished products containing L-Methylfolate. This information is kept as confidential and private by the Plaintiffs and derives independent economic value from not being generally known to the public or to the other persons or entities who could obtain economic value from its disclosure, and constitute trade secrets. Plaintiffs took reasonable steps to maintain the confidentiality of this information.

125. Plaintiffs produced confidential and highly confidential technical and business information about its L-Methylfolate Products, including information about product formulation, manufacturing test methods, pricing, profits and customers to Virtus during the *Virtus* litigation pursuant to a Protective Order that limited the use and dissemination of such information.

126. By holding himself out as *Virtus*' outside counsel during the *Virtus* Litigation; Bartel improperly acquired Plaintiffs' confidential and highly confidential technical and business information concerning their L-Methylfolate products.

127. Bartel intentionally and improperly acquired and thus misappropriated Plaintiffs' confidential information about Plaintiffs' L-Methylfolate Products in violation of the Texas Uniform Trade Secrets Act, TEX. CIV. PRAC. & REM. CODE ANN. § 134A ("TUTSA").

128. Bartel knew that the use and dissemination of Plaintiffs' confidential and highly confidential technical and business information concerning its L-Methylfolate products was strictly limited by the *Virtus* Court's Protective Order. As *Virtus*' counsel during the *Virtus* Litigation, Bartel was bound by the *Virtus* Court's Protective Order.

129. Bartel owed a duty to Plaintiffs to maintain the confidentiality of Plaintiffs' confidential information and to refrain from using said information to the direct detriment of Plaintiffs and for benefit of himself and Method.

130. Upon information and belief, Bartel gave Plaintiffs' confidential and highly confidential technical and business information concerning its L-Methylfolate products to Method without Plaintiffs' authorization or permission, in an effort to compete unfairly with Plaintiffs.

131. Method knew or had reason to know that Bartel had acquired information about Plaintiffs' L-Methylfolate Products pursuant to a protective order entered in litigation and had a duty to maintain its secrecy and limit its use.

132. Method acquired and thus misappropriated Plaintiffs' confidential information about Plaintiffs' L-Methylfolate Products in violation of the Texas Uniform Trade Secrets Act, TEX. CIV. PRAC. & REM. CODE ANN. § 134A ("TUTSA").

133. Whereas other manufacturers of so-called “generic” L-methylfolate products have failed in their efforts to develop stable and potent finished products, Method asserts that it has succeeded in developing stable L-Methylfolate products that are potent and do not rapidly degrade. Even if true, Method could not have succeeded in this endeavor without using Plaintiffs’ trade secrets, either at all or without substantial additional expenditures of time, labor and money.

134. Method’s wrongful use of Plaintiff’s confidential information about Plaintiffs’ L-Methylfolate Products further constitutes misappropriation in violation of the Texas Uniform Trade Secrets Act, TEX. CIV. PRAC. & REM. CODE ANN. § 134A (“TUTSA”).

135. Plaintiffs will suffer irreparable harm if Defendants are permitted to continue to have and use Plaintiffs’ misappropriated trade secrets. Plaintiffs have no adequate remedy at law for this conduct and is thus entitled to injunctive relief pursuant to TEX. CIV. PRAC. & REM. CODE ANN. § 134A.003.

136. As a proximate result of Defendants’ misappropriation of Plaintiffs’ trade secrets, Defendants have damaged Plaintiffs and have been unjustly enriched.

137. The aforementioned conduct of Defendants was done with oppression, fraud and malice toward Plaintiffs. Pursuant to TEX. CIV. PRAC. & REM. CODE ANN. § 134A.004, Plaintiffs are therefore entitled to recover exemplary damages from Defendants and each of them in an amount to be determined according to proof at trial.

138. Defendants’ acts are willful, wanton and are undertaken in bad faith, making Plaintiffs entitled to recover reasonable attorneys’ fees pursuant to TEX. CIV. PRAC. & REM. CODE ANN. § 134A.005.

#### **IV. JURY DEMAND**

Plaintiffs demand a trial by jury of all issues so triable.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully pray for the following relief:

- A. The Court enter a judgment and an order temporarily, preliminarily and permanently enjoining Defendants, their agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, from directly or indirectly falsely or misleadingly advertising or promoting Defendants' L-Methylfolate Products or inducing others to substitute Defendants' L-Methylfolate Products for prescriptions written for the NHS Products;
- B. The Court enter a judgment and an order temporarily, preliminarily and permanently enjoining Defendants, their agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, from making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of Defendants' L-Methylfolate Products in such fashion as to suggest that Defendants' L-Methylfolate Products have the same ingredients in the same amounts as Plaintiffs' L-Methylfolate Products; are generic or equivalent to Plaintiffs' L-Methylfolate Products; can be freely interchanged with or substituted for prescriptions written for the NHS Products; or are drugs;
- C. The Court enter a judgment and an order requiring Defendants to take corrective action to correct any erroneous impression persons may have derived concerning the nature,

characteristics or qualities of Defendants' L-Methylfolate Products, including without limitation the placement of corrective advertising;

D. The Court enter a judgment and an order granting Plaintiffs such other relief as the Court may deem appropriate to prevent the trade and public from deriving any erroneous impression concerning the nature, characteristics, qualities or benefits of Defendants' L-Methylfolate Products in comparison to Plaintiffs' L-Methylfolate Products;

E. The Court enter a judgment and an order requiring Defendants to pay Plaintiffs' damages in the amount of Plaintiffs' actual and consequential damages resulting from Defendants' false and misleading advertisements and marketing and unfair competition pursuant to 15 U.S.C. § 1117(a), and the common law of the State of Texas, and any profits resulting from Defendants' advertisements and marketing of its products;

F. The Court enter a judgment and an order finding that that this is an exceptional case and requiring Defendants to pay Plaintiffs additional damages equal to three times the actual damages awarded Plaintiffs pursuant to 15 U.S.C. § 1117(a) and all of Plaintiffs' reasonable attorneys' fees, costs and expenses, including those available under 15 U.S.C. § 1117(a), and any other applicable law;

G. The Court enter a judgment and order that Defendants and their agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from interfering with Plaintiffs' settlement agreement with Virtus and inducing breaches of that agreement by Virtus, Bartel and/or Rosenthal;

H. The Court enter a judgment and order that Defendants and their agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation

with them, be preliminarily and permanently enjoined from interfering with NHS's business relationship with Virtus;

I. The Court enter a judgment and order requiring Defendants to pay compensatory damages in tort for the interference with Plaintiff's contractual rights and business relations;

J. The Court enter a judgment and an order finding that Defendants acted maliciously, wantonly and/or fraudulently, requiring Defendant to pay Plaintiffs punitive damages pursuant to the common law of the State of Texas;

K. The Court enter a judgment and order that Defendants, their agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from maintaining, using, disclosing or otherwise disseminating Plaintiffs' trade secret information, or from offering to do so, or from attempting, causing or assisting anyone else in doing so, and ordering them to immediately return any documents or other data compilations of any form containing same to Plaintiffs;

L. The Court enter a judgment and order requiring Defendants to pay Plaintiffs damages in the amount of Plaintiffs' actual and consequential damages and any unjust enrichment by Defendants resulting from their misappropriation of Plaintiffs' trade secret information;

M. The Court enter a judgment and an order finding that that Defendants' actions are willful and malicious and requiring Defendants to pay Plaintiffs exemplary damages equal to two times the actual damages awarded Plaintiffs pursuant to TEX. CIV. PRAC. & REM. CODE ANN. § 134A.004;

N. The Court enter an order finding that Defendants' actions are willful, malicious and/or were undertaken in bad faith, and requiring Defendants to pay Plaintiffs' reasonable attorneys' fees pursuant to TEX. CIV. PRAC. & REM. CODE ANN. § 134A.005(3);

O. The Court enter a judgment and an order requiring Defendants to pay Plaintiffs pre-judgment and post-judgment interest on the damages awarded; and

P. The Court enter a judgment and an order awarding Plaintiffs such other and further relief as the Court deems just and equitable.

Dated: March 29, 2016

Respectfully submitted,

*s/Saul Perloff*

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*Attorneys for Plaintiffs*

**Nestlé Health Science – Pamlab, Inc. and  
Breckenridge Pharmaceutical, Inc.**

**CERTIFICATE OF SERVICE**

I hereby certify that I caused the foregoing to be electronically filed with the Clerk of the Court using the ECF-system for the Northern District of Texas and that the ECF-system will send a Notice of Electronic Filing to the following CM/ECF participant(s) on this the 29th day of March, 2016:

**Counsel for Defendant:**

Christopher J. Schwegmann

**By Email:**

cschwegmann@lynllp.com

*s/Saul Perloff*

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Saul Perloff

*Attorneys for Plaintiffs*